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 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 10/627,978
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 Olaf Ritzeler
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 EXAMINER

Carol P. Einaudi FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 1300 I Street, N.W. Washington, DC 20005-3315

DAVIS, ZINNA NORTHINGTON

ART UNIT PAPER NUMBER

1625 DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

| Application No. | Applicant(s) | Applicant(s) | | |
|-------------------------|-----------------|-----------------|--|--|
| 10/627,978 | RITZELER ET AL. | RITZELER ET AL. | | |
| Examiner | Art Unit | | | |
| Zinna Northington Davis | 1625 | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATISTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM

| THE N - Exten after S - If the - If NO - Failur - Any re | MAILING DATE OF THIS COMMUN sisons of time may be available under the provision of time may be available under the provision SIX (6) MONTHS from the mailing date of this comperiod for reply specified above is less than thirty period for reply is specified above, the maximum set or reply within the set or extended period for repeply received by the Office later than three months of patent term adjustment. See 37 CFR 1.704(b). | NICATION. as of 37 CFR 1.136(a). In no evimunication. (30) days, a reply within the statestatutory period will apply and willy will, by statute, cause the app | ent, however, may a reply be to utory minimum of thirty (30) do Il expire SIX (6) MONTHS fro lication to become ABANDON | timely filed ays will be considered timely. m the mailing date of this commur IED (35 U.S.C. § 133). | nication. |
|--|--|--|--|--|-------------|
| Status | b patient term adjustment. God or or it inverto). | | | | |
| 1)[_ | Responsive to communication(s) | filed on | | | |
| 2a)□ | This action is FINAL . | 2b)⊠ This action is | non-final. | | |
| 3)∐ Dispositie | Since this application is in condition closed in accordance with the praction of Claims | | | | erits is |
| · | Claim(s) 35-69 is/are pending in the | ne application. | | | |
| • | 4a) Of the above claim(s) is/ | • • | nsideration. | | |
| | Claim(s) is/are allowed. | | | | |
| | Claim(s) is/are rejected. | | | | |
| | Claim(s) is/are objected to. | | | | |
| _ | Claim(s) 35-69 are subject to restri | ction and/or election re | equirement. | | |
| Application | on Papers | | | | |
| 9)[] 7 | The specification is objected to by t | ne Examiner. | | | |
| 10)[] 7 | The drawing(s) filed on is/are | e: a) accepted or b) | objected to by the Ex | aminer. | |
| | Applicant may not request that any o | bjection to the drawing(s) | be held in abeyance. | See 37 CFR 1.85(a). | |
| 11) 🔲 🗆 | The proposed drawing correction file | ed on is: a) 🗌 a | pproved b)⊡ disapp | roved by the Examiner. | |
| | If approved, corrected drawings are r | equired in reply to this O | fice action. | | |
| 12)[] 7 | The oath or declaration is objected | to by the Examiner. | | | |
| ⊃riority u | nder 35 U.S.C. §§ 119 and 120 | | | | |
| 13)[| Acknowledgment is made of a clair | m for foreign priority ur | der 35 U.S.C. § 119 | (a)-(d) or (f). | |
| a)[| All b) Some * c) None of: | | | | |
| | 1. Certified copies of the priorit | y documents have bee | n received. | | |
| | 2. Certified copies of the priorit | y documents have bee | n received in Applica | ation No | |
| | 3. Copies of the certified copies application from the Interest the attached detailed Office active. | national Bureau (PCT | Rule 17.2(a)). | • | je |
| | cknowledgment is made of a claim | | · | • | lication) |
| • - |) \square The translation of the foreign la | | _ | . , | ilication). |
| | Acknowledgment is made of a claim | | • | | |
| Attachment | _ | | - · - · - · · · · · · · · · · · · · · · | | |
| 2) 🔲 Notice | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review nation Disclosure Statement(s) (PTO-1449) | | | ary (PTO-413) Paper No(s) al Patent Application (PTO-152 | |

Application/Control Number: 10/627,978

Art Unit: 1625

Election/Restriction

Page 2

1. Claims 35-69 are pending.

- 2. Restriction is required to one of the following inventions under 35 U.S.C. 121:
 - I. Claims 35-51, drawn to a compound, composition, process according to formula I.
 - II. Claims 52-65, drawn to a method of using a compound of formula I.
 - III. Claim 66, drawn to another method of using a compound of formula I.
 - IV Claim 67, drawn to a method for preparing a pharmaceutical consisting of a compound according to formula I.
 - V. Claim 68, drawn to a method for preparing a pharmaceutical consisting of a compound according to formula II.
 - VI. Claim 69, drawn to another method of preparing a pharmaceutical using a compound of formula II.
- 3. Inventions I-VI are related as product claims. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. For instance, see claim 66 wherein various disorders are claimed.
- 4. Inventions (IV-VI) and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

Art Unit: 1625

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. See claims 67-69.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: B₆, B₇, B₈, B₉, R₁, R₂, R₃, R₄, R₅, R₆, R₇, and R₈.

The ring system and radicals within the definition of B_6 , B_7 , B_8 , B_9 , R_1 , R_2 , R_3 , R_4 , R_5 , R_6 , R_7 , and R_8 are diverse in scope. A prior art reference, which anticipates one member such as phenyl under 35 U.S.C. 102, would not render obvious another member such as carboxyl under 35 U.S.C. 103. Accordingly, the ring systems and the radicals are independent and patentably distinct.

6. Applicant is required under 35 U.S.C. § 121 to elect *a single disclosed species* for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 35-69 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If

Application/Control Number: 10/627,978

Art Unit: 1625

claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 8. Due to the complexity of the restriction/election of species requirement, a written request is made.
- 9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.

Application/Control Number: 10/627,978

Art Unit: 1625

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zinna Northington Davis
Primary Examiner
Art Unit 1625

Page 5

Znd 9.02.2004